Supreme Court, U.S.
FILED
SEP 23 1999
OFFICE OF THE CLERK

No. 99-337

IN THE

Supreme Court of the United States

JANIS SOWERBY, As Personal Representative of the Estate of SCOTT MICHAEL HINKLEY, deceased, KAREN BOULAHANIS, GEORGE BOULAHANIS, individually and as next friend of BRIDGIT BOULAHANIS, a minor, KARA BOULAHANIS, a minor and BRIAN BOULAHANIS, a minor,

Petitioners,

v.

PREVO'S FAMILY MARKET, INC. a Michigan Corporation; I.B.P., INC. a Foreign Corporation and SPARTAN STORES, INC., a Michigan Corporation, Jointly and Severally,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE MICHIGAN COURT OF APPEALS

BRIEF IN OPPOSITION FOR RESPONDENT PREVO'S FAMILY MARKET, INC.

LANCE R. MATHER
Counsel of Record
SMITH, HAUGHEY, RICE & ROEGGE
Attorneys for Respondent
Prevo's Family Market, Inc.
200 Calder Plaza Building
250 Monroe, NW, Suite 200
Grand Rapids, MI 49503
(616) 774-8000

155029

Counsel Press LLC
FORMERLY LUTZ APPELLATE SERVICES
(800) 274-3321 • (800) 359-6859

STATEMENT OF QUESTION INVOLVED

Whether the Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, preempts the petitioners' state law claims for negligence and breach of warranty and the respondents are, therefore, entitled to a summary disposition dismissing those claims.

STATEMENT PURSUANT TO RULE 29.6

Respondent, Prevo's Family Market, Inc., has no parent corporation and no publicly held company owns 10% or more of its stock.

TABLE OF CONTENTS

	Page
Statement of Question Involved	i
Statement Pursuant to Rule 29.6	ii
Table of Contents	iii
Table of Cited Authorities	vii
Statement of the Case	1
1. The Boulahanis Case.	1
2. The Sowerby Case.	1
3. The Respondents.	1
4. The Petitioners' Claims.	1
5. Prevo's Motions for Summary Disposition.	1
6. The Trial Court's Decision.	2
7. The Decision of the Michigan Court of Appeals.	3
8. The Decision of the Michigan Supreme Court.	4
Reason for Denying the Writ	4

Contents

Page

The Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, Preempts The Petitioners' State Law Claims For Negligence And Breach Of Warranty And The Respondents Are, Therefore, Entitled To A Summary Disposition Dismissing Those Claims. 4

1. The Preemption Doctrine. 4

2. The Preemption Provision of the FMIA, 21 U.S.C. § 678. 5

3. The FMIA Has Preemptive Effect in this Case. 6

   A. The Petitioners' Arguments Rest on an Incorrect Assumption and Are Invalid for that Reason. 6

   B. The Michigan Supreme Court Properly Decided *Ryan v. Brunswick Corp*, 454 Mich. 20, 557 N.W.2d 541 (1997), and the Michigan Court of Appeals Properly Relied on that Decision When It Concluded that Federal Law Preempts the Petitioners' Claims. 10

Contents

Page

C. Even If the Federal Government Had Not Established a Policy Concerning Meat Contaminated with E. Coli Prior to 1994, State Regulation of Meat Containing Such Bacteria Would Still Have Been Preempted. 12

D. The FMIA Was Intended by Congress to Be Completely Preemptive. 15

E. Michigan Did Not Have Concurrent Jurisdiction to Make Laws and Regulations Concerning the Meat Involved in this Case. 16

F. Given the Petitioners' Failure to Recognize that this Case Involves Preemption Arising From Congressional Mandate, Rather than from the Mere Conflict Between State and Federal Laws, Many of Their Arguments Are Irrelevant. 17

4. The Petitioners' Reliance on the Decisions in the Medtronic and Freightliner Cases Is Unfounded, and Those Cases Do Nothing to Support Their Position in This Matter. 19

Contents

Page

5. Neither the Petitioners' First Argument Nor Their Unsubstantiated Claim that They Alone Have Been Denied a Remedy for Exposure to Meat Containing E. Coli States a Valid Reason Why Their Claims Should Not Have Been Dismissed. 26

6. The Petitioner's Argument Based on What This Court Might Have Done in *Lewis v. Brunswick*, No. 97-288, Has No Merit. 27

Conclusion 29

TABLE OF CITED AUTHORITIES

Page

Cases:

American Public Health Ass'n. v. Butz, 511 F.2d 331 (5th Cir. 1975) 8, 10

Armour & Co. v. Ball, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973) . 13, 14, 15, 16, 17, 21

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 11

English v. General Electric Co., 496 U.S. 72 (1990) 5

Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) 19, 23, 25

Lewis v. Brunswick Corp., 197 F.3d 1494 (11th Cir. 1997) 27, 28

Medtronic, Inc v. Lohr, 518 U.S. 470, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) 2, 19, 20, 21, 22, 23, 25

Ray v. Atlantic Richfield Co., 435 U.S. 151 (1978) 8

Ryan v. Brunswick Corp, 454 Mich. 20, 557 N.W.2d 541 (1997) 3, 10, 11, 12

Cited Authorities

Page

San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236 (1959) 11

Texas Food Industry Ass'n. v. Espy, 870 F. Supp. 143 (W.D. Tex. 1994) 9, 10

Statutes and Rules:

15 U.S.C. § 1381 *et seq.* 23

15 U.S.C. § 1392(d) 24

21 U.S.C. § 301 *et seq.* 19

21 U.S.C. § 360k(a) 19

21 U.S.C. §§ 601 *et seq.* ..... i, 2, 4

21 U.S.C. § 601(m) 8, 10

21 U.S.C. § 601(n)(7) 16

21 U.S.C. § 601-695 2

21 U.S.C. § 678 ..... 5, 7, 11, 12, 14, 16

M.C.L. 289.582(a)(1) 13, 14

M.C.L. 289.582(1)(e) 13

Cited Authorities

Page

M.S.A. 12.964(2)(a)(1) 13, 14

M.S.A. 12.964(2)(1)(e) 13

MCR 2.116(C)(10) 1, 2

STATEMENT OF THE CASE

1. The Boulahanis Case.

The Boulahanis case arises out of injuries to several minor petitioners allegedly caused by their consumption of ground beef infected with the bacteria Escherichia coli 0157:H7 ("E. coli"). That beef was allegedly purchased at respondent Prevo's Family Market, Inc. ("Prevo's").

2. The Sowerby Case.

The Sowerby case arises out of the death of petitioner's son. As in *Boulahanis*, this injury allegedly resulted from the consumption of ground beef infected with E. coli bacteria. Once again that beef was allegedly purchased at Prevo's.

3. The Respondents.

Respondent Prevo's Family Market, Inc., is an individually-owned chain of stores in the northwest region of Michigan that operates a supermarket in Mason County, Michigan. The two remaining respondents are I.B.P., Inc., a slaughterhouse and Spartan Stores, Inc., a distributor of food products.

4. The Petitioners' Claims.

As a consequence of their injuries, the petitioners filed suit against the respondents in the Circuit Court for Mason County Michigan. The petitioners in both cases asserted claims for breach of implied warranty of merchantability and various forms of negligence.

5. Prevo's Motions for Summary Disposition.

In response to the petitioners' complaints in both *Boulahanis* and *Sowerby*, respondent Prevo's filed motions for summary disposition pursuant to Michigan court rule MCR

2.116(C)(10). Those motions were based on the following contentions:

A. The petitioners' claims in both cases were based on allegations that Prevo's had sold ground round steak that was contaminated with E. coli bacteria.

B. The Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, as amended by the Wholesome Meat Act, 21 U.S.C. § 601-695, ("FMIA" or "the Act") specifically prohibits Michigan from imposing conflicting standards or requirements on a retail establishment for adulterant determination, inspection, labeling, or warning.

C. E. coli bacteria was not deemed to be an "adulterant" in July 1993 within the meaning of the FMIA.

D. Michigan law is preempted by the FMIA and under the FMIA the petitioners have no valid claim against Prevo's.

6. The Trial Court's Decision.

The trial court heard Prevo's motion for summary disposition on April 22, 1996. After the court heard oral argument and later reviewed supplemental briefs it had requested concerning the so-called "Jack-in-the-Box" cases, the court concluded that Prevo's motion should be granted; and it did so in an order entered on June 25, 1996.

The petitioners subsequently filed a Motion for Rehearing and Reconsideration, claiming that the decision of the United States Supreme Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) required a different conclusion on the question of preemption; but the trial court disagreed with that contention and denied the petitioners' motions in an order entered August 12, 1996.

The petitioners then appealed from the orders granting Prevo's a summary disposition and denying their Motion for Rehearing and Reconsideration.

7. The Decision of the Michigan Court of Appeals.

The Michigan Court of Appeals issued its decision in this matter on June 2, 1998 (Petitioners' Appendix A). In that decision the court concluded that the federal government's refusal to declare E. coli an "adulterant" until 1994 had the force of a positive determination that inspection of meat for E. coli was not required. Thus, the Court of Appeals concluded that the petitioners' claims were preempted by federal law and that all of the respondents were entitled to a summary disposition of those claims.

> In *Ryan* [v *Brunswick Corp*, 454 Mich. 20; 557 N.W.2d 541 (1997)] p 35, the Supreme Court made it clear that when a federal agency "has deliberately concluded that regulation is not appropriate in a given area, federal inaction will preempt state law not identical to it." That principle applies here. As previously noted, until 1994, the USDA did not consider E. coli to be an "adulterant." Therefore, the Department did not consider it necessary to inspect for E. coli and allowed the distribution of E. coli contaminated meat. The justification was that the painstaking microscopic inspection of meat for pathogens such as E. coli and salmonella was not feasible and not warranted when any bacteria would eventually be destroyed by the consumer upon proper preparation and cooking of the meat. See *American Public Health Ass'n* v *Butz*, 167 U.S. App. D.C. 93; 511 F.2d 331, 332, 334 (1974). This intentional decision, not to regulate the presence of E. coli because it was not considered an adulterant, carries the force of a positive enactment. *Ryan*,

> *supra*. Holding defendants liable for failing to detect the presence of E. coli bacteria in the meat purchased by petitioners in 1993 would run contrary to the USDA's then-existing determination that inspection for E. coli bacteria was not required. The trial court therefore properly concluded that petitioner's claims were preempted by federal law.

Boulahanis v. Prevo's Family, Market, Inc., 230 Mich. App. 131, 137, 583 N.W. 2d 509 (1998).

8. The Decision of the Michigan Supreme Court.

The petitioners then sought to have the Michigan Supreme Court review the decision rendered by the Court of Appeals, but the Supreme Court denied their request for such review in an order issued on March 30, 1999 (Petitioners' Appendix F).

REASON FOR DENYING THE WRIT

THE FEDERAL MEAT INSPECTION ACT, 21 U.S.C. §§ 601 *et seq.*, PREEMPTS THE PETITIONERS' STATE LAW CLAIMS FOR NEGLIGENCE AND BREACH OF WARRANTY AND THE RESPONDENTS ARE, THEREFORE, ENTITLED TO A SUMMARY DISPOSITION DISMISSING THOSE CLAIMS.

1. The Preemption Doctrine.

There are three circumstances in which federal law preempts state law:

> First, Congress can define explicitly the extent to which its enactments pre-empt state law. * * * Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. * * * Finally, state law is pre-empted to the extent that it actually

> conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

English v. General Electric Co., 496 U.S. 72, 78-79 (1990).

2. The Preemption Provision of the FMIA, 21 U.S.C. § 678.

21 U.S.C. § 678 contains the preemption provision of the FMIA. It provides as follows:

> Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are *in addition to, or different than* those made under this chapter may not be imposed by any State * * * . Marking, labeling, packaging, or ingredient requirements *in addition to, or different than*, those made under this chapter may not be imposed by any State * * * but any State * * * may, *consistent with the requirements under this chapter*, exercise *concurrent jurisdiction* * * * for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment * * * . This chapter shall not preclude any State * * * from making requirements or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

21 U.S.C. § 678 (emphasis added).

It is clear from this material that the FMIA forbids the states to impose inspecting, marking, labeling, or packaging requirements that are "in addition to or different than" those contained in the Act.

It is also clear that the instant cases involve the first type of preemption described above — preemption resulting from an express Congressional declaration that the FMIA and any regulations based on it shall have preemptive effect.

The petitioners consistently overlook this fact; and, as a consequence of their doing so, virtually all of their arguments fail to discuss the issues actually involved in this appeal. The petitioners' arguments might be suitable in cases involving preemption that results from the mere conflict of state and federal laws, but those arguments say nothing that is relevant to cases in which preemption is expressly mandated by the federal statute itself.

3. The FMIA Has Preemptive Effect in this Case.

A. *The Petitioners' Arguments Rest on an Incorrect Assumption and Are Invalid for that Reason.*

The petitioners' petition is largely devoted to a single argument which they restate a number of times in somewhat different fashion. The argument asserts that the doctrine of preemption does not apply in this case because prior to 1994 the federal government had supposedly failed to make any regulations concerning meat containing E. coli bacteria. The following statements from the petitioners' petition are illustrative of their repeated claims to that effect.

> * * * Thus, where the condition of which the Petitioners complain, and as to which the Petitioners assert common law theories of recovery, is not federally regulated, and is the

> subject to no federal requirements, either directly under the statute or by regulation, state law claims should be allowed.

(Petition, pp. 13-14.)

* * *

> * * * That the Federal government had not yet determined, at the time of Petitioners' consumption of the meat, that the meat was adulterated for having E. coli within it does not mean that it was not, in fact and in law, adulterated prior to that time.

(Petition, p. 15.)

* * *

> * * * There was no Federal regulation or regulatory action by the Federal Meat Inspection Agency prior to 1994. * * *

(Petition, p. 17.)

The arguments the petitioners base on the alleged failure of the federal government to regulate meat containing E. coli bacteria are erroneous for several reasons.

First of all, they are irrelevant to the issues involved in this appeal because the preemption involved in the underlying cases is mandated by 21 U.S.C. § 678. The preemptive effect of the FMIA thus does not depend in any way on the existence of a conflict between state and federal laws; and it is consequently immaterial whether, prior to 1994, the federal government had decided whether meat containing E. coli was adulterated. The FMIA has preemptive effect because it is a federal statute and says that it preempts state law. Nothing more is needed.

The petitioners further err in claiming that prior to 1994 the federal government had not spoken on the issue of E. coli in meat. Thus, the fundamental assumption underlying virtually all of their arguments is simply wrong.

The fact that, prior to 1994, the United States Department of Agriculture ("USDA") declined to classify meat containing E. coli bacteria as "adulterated" was fully equivalent to an affirmative decision that such meat was not "adulterated" and could be sold for human consumption. The petitioners' attempt to transform this obviously deliberate decision by the USDA into a failure to act is nonsense.

After all, 1993 was not that long ago; and the dangers associated with the contamination of food by E. coli were well known at that time. 1994 was not the year when the USDA first become aware of the dangers posed by meat containing E. coli, and it had undoubtedly considered the status of E. coli as an adulterant before that time. As long ago as 1975 the status of salmonella bacteria as an "adulterant" was litigated, and it was decided that the presence of salmonella in meat did not constitute adulteration within the definition established by 21 U.S.C. § 601(m). *American Public Health Ass'n. v. Butz*, 511 F.2d 331, 334 (5th Cir. 1975). The presence of bacteria in meat was clearly an issue that has occupied the USDA for many years, and the petitioners' repeated assertions that the USDA never gave any thought to the status of E. coli as an adulterant and made no decision on that question prior to 1994 is clearly wrong.

Furthermore, the Supreme Court of the United States has expressly recognized that a decision not to regulate is itself regulation whenever the federal government intended to centralize all authority over the regulated area in one decision maker; and that is precisely the situation where the USDA and regulation of standards for meat are concerned. *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978).

Unfortunately for the petitioners' arguments in this case, until 1994 the USDA held the view that meat containing E. coli bacteria was not adulterated; but its doing so is obviously far different from making no decision at all on that question.

The court in *Texas Food Industry Ass'n. v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994) properly interpreted the USDA's decision in 1994 to declare E. coli an adulterant and labeled that decision a change in its prior policy of viewing meat containing E. coli as not adulterated.

> * * * Prior to this announcement, the USDA had treated pathogen-contaminated meat as unadulterated under the FMIA.

870 F. Supp. 143, 145.

* * *

> * * * Finally, the Court finds that the Defendants' changing policy is a rational response to an emerging problem.

870 F. Supp. 143, 148.

The court in *Texas Food* also pointed out that the USDA had been sampling and testing meat for E. coli bacteria for several years before declaring that bacteria an adulterant (870 F. Supp. 143, 146, fn. 6), and obviously the presence of E. coli in meat had been a matter of concern to the USDA for a considerable amount of time before it declared such bacteria an adulterant in 1994.

A decision not to label certain meat as adulterated is a decision even though it results in no action; and when, prior to 1994, the USDA declined to label meat containing E. coli as adulterated it made a decision that such meat was not, in fact,

adulterated. The petitioners' repeated claims to the contrary have no merit and are clearly wrong.

B. *The Michigan Supreme Court Properly Decided Ryan v. Brunswick Corp, 454 Mich. 20, 557 N.W.2d 541 (1997), and the Michigan Court of Appeals Properly Relied on that Decision When It Concluded that Federal Law Preempts the Petitioners' Claims.*

The decision in *Ryan v. Brunswick Corp.*, 454 Mich. 20, 557 N.W.2d 541 (1997) shows quite clearly that federal law preempts the petitioners' claims. *Ryan* properly concluded that a refusal to regulate can itself be considered a form of regulation, especially where no federal standards or requirements are imposed even after a particular problem has been identified and studied. That portion of *Ryan*'s holding is based on solid federal precedent and is consistent with well-established law. 454 Mich. 20, 35-36.

This part of *Ryan*'s holding provides the answer to the petitioners' repeated assertions that no preemption can occur in this case because prior to 1994 the USDA did not consider E. coli bacteria to be an adulterant. The USDA certainly knew that the presence of such bacteria in meat presented a possible problem, and it studied that problem for several years before declaring E. coli an adulterant. *See Texas Food Industry Ass'n. v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994). *See also American Public Health Ass'n. v. Butz*, 511 F.2d 331, 334 (5th Cir. 1975). (Salmonella bacteria was not an adulterant in meat as that term is defined in 21 U.S.C. § 601(m)).

Given this awareness of the possible problem posed by E. coli in meat and the study of that problem prior to 1994, the USDA's decision not to declare E. coli an adulterant was fully equivalent to an express decision that it was not then an adulterant. Thus, even if it were necessary for the federal government to exert its regulatory power in this area for

preemption to occur (a clearly incorrect assumption given the nature of the express preemption provision found in 21 U.S.C. § 678), such regulation did in fact occur; and the decision in *Ryan* strongly supports that conclusion. The petitioners' claims to the contrary are clearly wrong.

Ryan also holds that "state law" includes common law actions for damages. This conclusion is also clearly correct and is, once again, based on established federal precedent. A common law action may be a form of state law or regulation that is preempted by federal law because the possibility of a damage award can compel someone to do something federal law does not require. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236 (1959).

This portion of *Ryan* answers the petitioners' claims that their common law claims somehow fall outside the scope of the preemption doctrine and survive despite it.

The petitioners' analysis of *Ryan* is furthermore dead wrong because it ignores the nature of the preemption provision involved in that case. By doing so it fails to comprehend the question actually presented in that case.

Given the preemption provision and saving clause involved in the Federal Boat Safety Act, the Supreme Court of Michigan in *Ryan* concluded that preemption occurred only when a state law or regulation was not identical to an *existing* federal regulation (454 Mich. 20, 30, fn. 12). Thus, in *Ryan* it was necessary for a federal regulation inconsistent with a state law or regulation to exist before preemption could take place. It was for that reason that the Michigan Supreme Court considered the intention of Congress in deciding not to require guards on boat propellers. In order to answer the preemption question presented in *Ryan* it was necessary to determine whether the refusal of Congress to require such guards was equivalent to an express determination that such guards were not necessary.

This case necessitates no such inquiry. The preemption provision involved in this matter expressly prohibits a state from enacting any requirement "in addition to" those imposed by the FMIA, and thus it is not necessary to find a conflict between a state law or regulation and an existing federal regulation before preemption occurs. The preemption provision in 21 U.S.C. § 678 invalidates any state law or regulation that imposes an additional "marking, labeling, packaging, or ingredient" obligation on any entity subject to the FMIA regardless of whether the federal government has enacted any regulations in that area or not. The petitioners' claim that a *Ryan*-type analysis of Congressional intent is required in this case thus has no merit.

C. *Even If the Federal Government Had Not Established a Policy Concerning Meat Contaminated with E. Coli Prior to 1994, State Regulation of Meat Containing Such Bacteria Would Still Have Been Preempted.*

Any Michigan law concerning meat containing E. coli would have been preempted in 1993 even if the federal government had failed to determine that such meat was not adulterated. The FMIA does not merely prohibit state laws and regulations that are "different than" those established by the federal government. It also prohibits laws and regulations "in addition to" those set forth in the FMIA. This fact is fatal to the petitioners' arguments.

Any Michigan provision that concerned the marking, labeling, packaging, or ingredient requirements of the meat involved in this case would necessarily have been "in addition to" the requirements of the FMIA and would have been preempted for that reason. This conclusion is independent of any federal statute or regulation concerning meat containing E. coli and does not depend upon the existence of federal action concerning such meat.

The fact that the FMIA prohibits any state regulation "in addition to" its own provisions demonstrates a fundamental error

in the petitioners' arguments. They have treated this case as one that involves only an actual conflict between federal and state law; and, having supposedly demonstrated that there is no conflict, they claim that preemption has not occurred.

There are two errors inherent in the petitioners' approach. First, there is an actual conflict because, prior to 1994, the federal refusal to label meat containing E. coli as adulterated was fully equivalent to an affirmative decision that such meat was not adulterated. Second, given the FMIA's prohibition against state provisions "in addition to" its own, no actual conflict between state and federal law was necessary for preemption to occur. Preemption took place because the FMIA specifically said it did, and that expression of Congressional will was more than sufficient to effect preemption in this case.

The preemptive effect of the FMIA on state law and regulations "in addition to" its own is also made clear by the decision in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973), which struck down major portions of Michigan's Comminuted Meat Law.

Although certain portions of the Comminuted Meat Law conflicted directly with federal regulations, a number of its provisions did not do so. That fact notwithstanding, even the provisions that did not establish requirements different from federal regulations were found to be preempted.

For example, the federal regulations governing the ingredients in sausage did not establish a requirement for overall moisture or protein content (468 F.2d 76, 87). The Comminuted Meat Law did so, however. M.C.L. 289.582(a)(1); M.S.A. 12.964(2)(a)(1). (These provisions are now found in M.C.L. 289.582(1)(e); M.S.A. 12.964(2)(1)(e).)

Despite the absence of any direct conflict between the federal regulations and Michigan law, the portions of M.C.L.

289.582(a)(1); M.S.A. 12.964(2)(a)(1) establishing the standards for overall moisture and protein content were held to be preempted (468 F.2d 76, 85).

The same conclusion must be reached in this case. Even if the USDA had not taken the position that meat containing E. coli was unadulterated, a state law or regulation declaring such meat adulterated would necessarily have been preempted because the FMIA and the federal regulations based on it establish the only standards for determining whether such meat is, in fact, adulterated.

Although the petitioners' arguments concern only meat containing E. coli, those arguments obviously would apply just as well to any characteristic of meat that has not been regulated by the federal government. If the petitioners' arguments were correct, then a state could pass laws and enact regulations affecting any such characteristic simply because the federal authorities had not yet done so. Is such a conclusion possibly correct? Of course not. If a state passed such laws and regulations, they would necessarily be "in addition to" the standards imposed by the FMIA and would be preempted by reason of 21 U.S.C. § 678. Such laws and regulations would fare no better than the portions of Michigan's Comminuted Meat Law concerning overall moisture and protein content that were found to be preempted in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973).

The petitioners' arguments completely overlook the fact that the FMIA prohibits state laws and regulations "in addition to" its own, and their petition contains no discussion at all of that prohibition. By failing to recognize that the FMIA has preemptive force by its own terms, the petitioners have missed one of the most important points in this case.

D. *The FMIA Was Intended by Congress to Be Completely Preemptive.*

In addition to the language of the FMIA itself, the case law interpreting it demonstrates that Congress intended the FMIA to have completely preemptive effect. This conclusion is clearly set forth in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973). The decision in that case states in the most definite terms that the FMIA completely preempts state law within its sphere of operation.

> * * * Thus, by prohibiting a state's imposition of "marking, labeling ... or ingredient requirements" which are "in addition to or different than [those made by the Secretary]," Congress has "unmistakably ... ordained" that the Federal Act fixes the sole standards. * * *

468 F.2d 76, 84.

* * *

> Congressional debates are devoid of any discussion of Section 408 of the Act (21 U.S.C. § 678). However, in view of its unambiguous language, Section 408 reflects unequivocal legislative purpose to make the Federal Act preemptive.

468 F.2d 76, 84-85.

* * *

> * * * Nevertheless, in view of the clear and complete preemption ordained by Congress, this Court must enforce the Supremacy Clause and declare that the Federal Act preempts certain provisions of the Michigan law. * * *

468 F.2d 76, 85.

In this case, as in *Armour*, the FMIA established the "sole standards" and effected a "clear and complete preemption" of any Michigan law or regulation "in addition to, or different than" the FMIA's own provisions.

E. *Michigan Did Not Have Concurrent Jurisdiction to Make Laws and Regulations Concerning the Meat Involved in this Case.*

The petitioners err in claiming that 21 U.S.C. § 678 granted Michigan "concurrent jurisdiction" to regulate the meat involved in this case. Admittedly, 21 U.S.C. § 678 does say that " * * * any State may, consistent with the requirements under this chapter, exercise concurrent jurisdiction * * * for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded * * *." However, that provision did not apply to the meat involved in this case and could not possibly have conferred any jurisdiction on Michigan to regulate it.

The concurrent jurisdiction described in the quoted language applies only to "adulterated or misbranded" articles; and furthermore those terms must be given the meaning they have under federal, not state, law. This conclusion is clear from the decision in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973) in which the Court said this about the language quoted above.

> The concurrent action of a state, permitted by this language, only applies to adulterated or misbranded articles. These words are necessarily used as defined in the act. * * * Permissible concurrent enforcement by a state under Section 678 would apply only to meat food products that satisfy this definition of misbranding [*i.e.*, the definition in 21 U.S.C. § 601(n)(7)]. In its concurrent enforcement a state would not be

> permitted to prevent the distribution in commerce of any article that "conforms" to the "definition and standard of identity or composition." Thus, Congress is ordaining uniform national ingredient requirements prescribed by the Secretary.

468 F.2d 76, 84.

At the time the meat involved in this case was sold and consumed, federal regulations did not classify meat containing E. coli bacteria as adulterated. Given that fact, Michigan had no concurrent jurisdiction to regulate the handling, inspection, labeling or sale of such meat because it was not adulterated as that term is used in the FMIA. At the times relevant to these cases, Michigan likewise had no power to prevent the distribution of meat containing E. coli bacteria because such meat was then in full compliance with the requirements imposed by the FMIA. The petitioners' arguments to the contrary are clearly incorrect.

F. *Given the Petitioners' Failure to Recognize that this Case Involves Preemption Arising From Congressional Mandate, Rather than from the Mere Conflict Between State and Federal Laws, Many of Their Arguments Are Irrelevant.*

Because the petitioners have misconstrued the reason why federal law has preemptive effect in these cases, many of their arguments are irrelevant to the issues actually involved in this appeal. It is, for example, immaterial whether the USDA's regulations are comprehensive or not (Petition, p. 19). The FMIA does not preempt Michigan law because of any particular characteristic of the regulations based on it. It preempts Michigan law because it is a federal statute and expressly says that it has preemptive effect.

It is likewise immaterial whether the petitioners have a remedy to replace the one being precluded by the federal statute

(Petition, p. 11). The absence of such an alternative remedy is relevant only when preemption arises because of a perceived conflict between state and federal law. Where a federal statute expressly provides for preemption, there can be no doubt about the effect of that statute; and the absence of some other remedy is, therefore, irrelevant.

As the petitioners themselves admit in their petition:

> * * * Where there is a specific preemption provision in a Federal statute, there is no need to consider whether preemption should be implied from the law or from Federal regulations. The question at that point is the proper interpretation of the express preemption provision. *Cipollone* v *Liggett Group, Inc*, 505 US 504; 112 SCt 2608; 120 LEd 2d 407, 423 (1992). As noted in *Cipollone* (*id*):
>
> > When Congress has considered the issue of preemption and has included in the enacted legislation a provision explicitly addressing that issue, and when the provision provides a "reliable indicium of congressional intent with respect to state authority," * * * "there is no need to infer congressional intent to preempt state law from the substantive provisions of the legislation" (citations omitted).

(Petition, p. 11).

Respondent Prevo's agrees fully with the quoted material from the petition. The situation present in this appeal is furthermore identical to the one described in that material, and thus it applies directly to this matter.

The FMIA contains a "specific preemption provision," and in light of that fact there is no question that it preempts state law. All of the petitioners' arguments about what might possibly be presumed or inferred from the nature of the regulations based on the FMIA, from the absence of some other remedy to replace the one precluded by the FMIA, or from the alleged failure of the federal government to regulate meat containing E. coli until 1994 are, therefore, irrelevant.

4. The Petitioners' Reliance on the Decisions in the Medtronic and Freightliner Cases Is Unfounded, and Those Cases Do Nothing to Support Their Position in This Matter.

In their petition the petitioners place significant reliance on the decisions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995). That reliance is unfounded. Neither of those decisions supports the petitioners' arguments in this matter.

Medtronic involved claims for personal injury allegedly caused by a defective pacemaker lead. The defendant manufacturer responded with an argument that the claim was preempted by federal law because 21 U.S.C. § 360k(a) provides that no state may establish or continue in effect, with respect to a device intended for human use, any requirement that is different from, or in addition to, any requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. § 301 *et seq.*

The Supreme Court disagreed and held that the petitioners' claim was not preempted. It did so for a number of reasons, not one of which applies to this case.

First and foremost, the Court's decision was based in large part on the fact that the Food and Drug Administration (FDA) has broad power to determine when and to what extent a statute

in the FDCA or a regulation based on such a statute has preemptive effect. The FDA, unlike many other agencies, has even passed regulations that place significant restrictions on the extent to which preemption occurs.

> The FDA regulations interpreting the scope of § 360k's preemptive effect support the Lohrs' view, and our interpretation of the pre-emption statute is substantially informed by those regulations. * * * In addition, Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect. Unlike the statute construed in *Cipollone*, for instance, pre-emption under the MDA [Medical Devices Act] does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal "requirement." * * *

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2255, 135 L. Ed. 2d 700, 722 (1996).

The regulations enacted by the FDA furthermore provide that preemption does not occur unless the FDA has enacted its own regulations speaking to the very same subject as the state law that is supposedly preempted or some unavoidable conflict between state and federal law is certain to result.

> The Lohrs' theory is supported by the FDA regulations, which provide that state requirements are preempted "only" when the FDA has established "specific counterpart regulations or * * * other specific requirements applicable to a particular device." 21 CFR § 808.1(d)(1995). * * *

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2257, 135 L. Ed. 2d 700, 723 (1996).

* * *

> * * * The regulations even go so far as to state that § 360k(a) generally "does not preempt a state or local requirement prohibiting the manufacturing or adulterated or misbranded devices" unless "such a prohibition has the effect of establishing a substantive requirement for a specific device. § 808.1(d)(6)(ii) * * *"

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2257, 135 L. Ed. 2d 700, 724 (1996).

* * *

> Although we do not believe that this statutory and regulatory language necessarily precludes "general" federal requirements from ever pre-empting state requirements, or "general" state requirements from ever being pre-empted, see Part VI, *infra*, it is impossible to ignore its overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest. * * *

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2257, 135 L. Ed. 2d 700, 724 (1996).

This case involves nothing that is even close to the preemption doctrine that applies to the FDCA. The FMIA was intended by Congress to set the sole standards within its sphere of operation, and preemption occurs under the FMIA even if the federal government has not enacted laws or regulations concerning a particular question. *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973).

In *Medtronic* the Court also found preemption inapplicable because the petitioners were, in effect, seeking to use a state remedy to enforce a requirement that already existed under

federal law. In other words, the petitioners were looking to state law only for their remedy, not for the basis of their claim.

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, that the federal requirement. * * * The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2255, 135 L. Ed. 2d 700, 722 (1996).

In this case the situation is completely different. When the petitioners' claims arose in 1993, federal law did not consider meat containing E. coli bacteria adulterated; and thus the petitioners had no possible claim against respondent Prevo's under federal law. Indeed, the petitioners have even admitted that fact. See Part 4, *supra*.

The petitioners in this matter, unlike the petitioners in *Medtronic*, were not seeking a state remedy for violation of a federal requirement. They were likewise not seeking a state remedy for violation of a state requirement that was no broader than and essentially identical to one already existing under federal law.

To the contrary, they were seeking a state remedy for violation of a state requirement that was "in addition to" and "different than" the federal standard in effect at the time. Given that fact, the decision in *Medtronic*, based as it is on the fact that federal law established a requirement identical to the one under which the petitioners there sought to recover, does nothing to show that there is no preemption in this case.

The decision in *Medtronic* is obviously based on a statute and doctrine of preemption that are quite different from the ones involved in this case, and for that reason *Medtronic* simply does not apply to this matter. The petitioners' reliance on that decision is thus unfounded.

The decision in *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995) likewise fails to support the petitioners' arguments, and it does so for reasons similar to those affecting the decision in *Medtronic*.

Freightliner involved claims that certain tractor-trailers were negligently designed because they did not have antilock brake systems (ABS's). The manufacturer argued that these state law claims were preempted by the National Traffic and Motor Vehicle Safety Act of 1966 (the "Safety Act"), 15 U.S.C. § 1381 *et seq.* and its implementing regulations.

The Supreme Court disagreed and found no preemption. It did so for two reasons, neither of which exists in this case. First, the preemption provision in the Safety Act specifically provided that preemption occurred only when state and federal safety standards regulated the same aspect of performance of a vehicle or item of equipment and the standards were not identical.

> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to

> continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard. * * *

15 U.S.C. § 1392(d).

Second, at the relevant times, previously enacted federal standards concerning the required stopping distances for trucks had been suspended by order of the Ninth Circuit Court of Appeals.

Given the language of the Safety Act allowing preemption only when a federal standard regulating the same subject matter was in effect and the suspension of the federal standard for stopping distances, the Supreme Court found the requirements of the statute had not been satisfied.

> Despite the fact that Standard 121 remains suspended, petitioners maintain that defendants' lawsuits are expressly pre-empted. We disagree. The Act's pre-emption clause applies only "[w]henever a Federal motor vehicle safety standard * * * is in effect" with respect to "the same aspect of performance" regulated by the a state standard. 15 U.S.C. § 1392(d) [15 U.S.C.S. § 1391(d)]. There is no express federal standard addressing stopping distances or vehicle stability for trucks or trailers. No NHTSA regulation currently establishes a "minimum standard for * * * motor vehicle equipment performance," § 1391(2), nor is any standard "stated in objective terms," § 1392(a). There is simply no minimum, objective standard stated at all. Therefore, States remain free to "establish, or to continue in effect,"

> their own safety standards concerning those "aspects of performance." § 1392(d).

Freightliner Corp. v. Myrick, 514 U.S. 280, 286 (1995).

The FMIA contains no provision like the one in the Safety Act that limits preemption to situations where state and federal standards speak to the same subject matter. The FMIA provides just the opposite, in fact, by providing that preemption occurs whenever any state law or regulation is "in addition to, or different than" the provisions of the Act itself. Thus, under the FMIA, a state law or regulation is preempted if it is simply "in addition to" the provisions of the Act, regardless of whether any portion of the FMIA regulates the same subject as the state enactment. The situation in *Freightliner* was quite different; and, therefore, the decision in that matter says nothing about whether preemption occurred in this case.

In addition, the decision of the USDA not to label meat containing E. coli bacteria adulterated was fully equivalent to an affirmative decision that such meat was not, in fact, adulterated; and thus preemption would occur in this case even if the FMIA contained the sort of restrictive preemption provision found in the Safety Act at issue in *Freightliner*.

The petitioners' arguments thus find no support in *Medtronic* or *Freightliner*. The petitioners' discussion of those decisions fails even to mention, much less take account of, the fact that each of them involved a preemption provision that is far more restrictive than the one involved in this case and that the decisions in those matters were direct (and necessary) consequences of the restrictive preemption provisions they were applying.

5. Neither the Petitioners' First Argument Nor Their Unsubstantiated Claim that They Alone Have Been Denied a Remedy for Exposure to Meat Containing E. Coli States a Valid Reason Why Their Claims Should Not Have Been Dismissed.

The petitioners misdirect their first argument. If the current regulatory procedures for meat products present problems (Prevo's denies that they do), the petitioners should direct their complaints at Congress, which placed an express preemption provision in the FMIA, and the USDA, which is allegedly not acting quickly enough in identifying new pathogens and labeling them as adulterants.

The petitioners' complaints and "parade of horribles" do not provide any reason, much less justification, for any court to refuse enforcement of an express preemption provision in a federal statute. Congress has clearly stated that the FMIA shall have preemptive effect, and that fact cannot be changed by any problems the petitioners claim they have identified in the inspection and labeling procedures the FMIA establishes.

The E. Coli problems associated with the Jack-in-the- Box hamburger chain have no relevance to this case, and the petitioners' discussion of them proves nothing. Jack-in-the-Box is a fast food retailer, and its liability in the various cases brought against it was based on improper cooking of the hamburgers it served. The express preemption provision of the FMIA is concerned with "marking, labeling, packaging, and ingredient requirements"; and it has nothing at all to do with cooking. Thus, the preemption provision of that act did not apply to Jack-in-the-Box in any way. The decision in this case thus has no effect whatsoever on the possible liability of a retailer selling hamburgers or other finished food products for claims based on improper cooking. It is misleading of the petitioner to suggest otherwise.

The petitioners' claim that they are the only victims of E. coli poisoning in the United States to be denied a tort remedy is both undemonstrated and irrelevant. It is undemonstrated because the petitioners have not cited one single case in which someone injured before 1994 by meat containing E. coli was allowed to recover from an entity covered by the preemption provision of the FMIA. In other words, the petitioners have failed to show that any other jurisdiction has refused to give preemptive effect to the FMIA for an E. coli injury that occurred before the USDA declared E. coli to be and adulterant in meat.

The petitioners' claim is irrelevant for at least two reasons. First, to the extent that it is based on claims asserted against fast food retailers such as Jack-in-the-Box for improper cooking, it proves nothing because the preemption provision of the FMIA does not apply to cooking. Second, if other states have failed to recognize the preemptive effect of the FMIA, they have clearly erred by doing so. Their errors certainly provided no valid reason why the courts of Michigan should have repeated their mistakes.

6. The Petitioner's Argument Based on What This Court Might Have Done in *Lewis v. Brunswick*, No. 97-288, Has No Merit.

The petitioners' final argument is based on a claim that this Court might have reversed the decision *Lewis v. Brunswick Corp.*, 197 F.3d 1494 (11th Cir. 1997) if the case had not been settled prior to the release of an opinion. That argument has no merit.

The opinion of petitioner's counsel about what this Court might have done in a case in which no decision was ever rendered is speculative and totally irrelevant to any question involved in this case.

Furthermore, even if the Court had modified the decision of the Eleventh Circuit Court of Appeals in *Lewis v. Brunswick*

Corp., 197 F.3d 1494 (11th Cir. 1997), its decision would have had little, if any, relevance to this matter because of the different express preemption provisions contained in the Federal Meat Inspection Act (FMIA) and the Federal Boating Safety Act (FBSA).

The petitioners also place reliance on the amicus curiae brief of the Solicitor General submitted to this Court in *Lewis*. That reliance is unfounded. The arguments set forth in that brief are clearly statute specific, and their reasoning could not possibly apply to the express preemption provision in the FMIA because it differs significantly from the preemption provision in the FBSA.

In addition, it is axiomatic that the law is stated by the courts, not by the Department of Justice, the Solicitor General, or anyone else who takes a position on a particular issue for undisclosed reasons that may well have no connection whatsoever with the merits of that issue. The petitioners' attempt to use the position taken by the Solicitor General in the *Lewis* case as "authority" for their position thus necessarily fails.

CONCLUSION

For the reasons set forth above, respondent, Prevo's Family Market, Inc., respectfully requests the Court to deny the petition for a writ of certiorari.

Respectfully submitted,

LANCE R. MATHER
Counsel of Record
SMITH, HAUGHEY, RICE & ROEGGE
Attorneys for Respondent
Prevo's Family Market, Inc.
200 Calder Plaza Building
250 Monroe, NW, Suite 200
Grand Rapids, MI 49503
(616) 774-8000